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Intellectual Property Dept.
Dewitt Ross & Stevens SC
2 East Mifflin Street
Suite 600
Madison, WI 53703-2865

EXAMINER	
TANNER, JOCELIN C	
ART UNIT	PAPER NUMBER
3731	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket-ip@dewittross.com

Office Action Summary	Application No.	Applicant(s)	
	10/595,371	KEEBLE ET AL.	
	Examiner	Art Unit	
	JOCELIN C. TANNER	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-12,15-22 and 25-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-12,15-22 and 25-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/26/09, 10/05/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Amendment filed 21 September 2009. Claims 1, 5-12, 15-22 and 25-31 are currently pending. The Examiner acknowledges the amendments to claims 11, 16 and 30 and the cancellation of claims 2-4, 13, 14, 20, 21, 23 and 24.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 5, 7, 9, 10, 16, 17, 19, 22, 25 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belson (US PGPub No. 2003/0032859A1) in view of Wolfe (US Patent No. 5,486,127).

3. Regarding claims **1 and 30**, Belson discloses a device including a plurality of detachable, hingeably connected segments, each segment being hingeably connected to two adjacent segments or a single adjacent segment if at the end of the line, each segment connected by a ball-and-socket type joint wherein a male part engages within the socket of a female (0025, 0072, 0076], Fig. 7A). The endoscope of Belson may be inserted into a body cavity through a surgical tube such as a surgical cannula or introducer [0093]. Although Belson fails to expressly disclose the surgical tube as a catheter, it is well known in the art to introduce an endoscope into a body through a large diameter tube such as a catheter. A medical implant is capable of being attached

to an end of the device and can be advanced through the catheter by pushing the other end of the device. However, Belson fails to expressly disclose segments bearing a male part including a pair of projections and a female part including a socket with slots.

Wolfe teaches a system having a plurality of segments connected by ball-and-socket type joints, each segment including a male connector (2) and a female receptor(3), the male connector having adjoining keys (6) and the female receptor having key slots (9) that receive the key portions (column 3, lines 15-25, 48-50, column 4, lines 12-20, 26-39).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the balls and sockets of Belson with the projections and slots, as taught by Wolfe, to control the amount of displacement about the axis of the male and female connectors (column 3, lines 15-25).

The Examiner notes that the device of Belson is capable of having a medical implant mounted thereon to be advanced through a catheter. Regarding the limitation, “whereby a medical implant mounted at one end of the device can be advanced through a catheter by pushing on the other end of the device, the hinged connections allowing the device to follow a curved path through the catheter, characterized in that each segment is detachable from its adjacent segment(s)", the Examiner notes that the manner or method in which an device is to be utilized is not germane to the issue of patentability of the device itself (In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967)). Furthermore, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the

claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

4. Regarding claim **5**, the combination of Belson and Wolfe discloses segments that may be formed of stainless steel, thermoplastic polymers and plastics. The combination of Belson and Wolfe fails to expressly disclose segments formed from a material sufficiently stiff to allow a moment of at least 1 Newton metre to be transmitted through the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have formed the segments from a material sufficiently stiff to allow a moment of at least 1 Newton metre to be transmitted through the device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

5. Regarding claims **7**, Belson discloses a segment having an internal passage (84) that would allow a guide wire to pass therethrough ([0072], Fig. 7A).

6. Regarding claim **9**, the combination of Belson and Wolfe discloses a ratio of the length to the widest diameter of each segment that appears to be 1:1 to 1:5 (Fig. 7A).

7. Regarding claim **10**, the combination of Belson and Wolfe discloses that a slot may be wider than the projection to provide a controlled amount of displacement (column 3, lines 15-25). The combination of Belson and Wolfe discloses the claimed invention except for a maximum of 15 degrees of articulation between the longitudinal axes of two adjacent segments. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a maximum of 15

degrees of articulation between the longitudinal axes of two adjacent segments, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

8. Regarding claim **16,** Belson discloses a device including an endoscope that may be inserted into a body cavity through a surgical tube such as a surgical cannula or introducer [0093] that includes an interior passage therethrough. Although Belson fails to expressly disclose the surgical tube as a catheter, it is well known in the art to introduce an endoscope into a body through a large diameter tube such as a catheter. Belson further discloses the device including a plurality of detachable, hingeably connected segments arrayed in a line, each segment pivotably abutting adjacent segments whereby the line of segments are capable of adopting a curved path within the catheter, each segment connected by a ball-and-socket type joint wherein a male part engages within the socket of a female (0025, 0072, 0076], Fig. 7A). A medical implant is capable of being attached to an end of the device and can be advanced through the catheter by pushing the other end of the device. However, Belson fails to expressly disclose segments bearing a male part including a pair of projections and a female part including a socket with slots.

Wolfe teaches a system having a plurality of segments connected by ball-and-socket type joints, each segment including a male connector (2) and a female receptor(3), the male connector having adjoining keys (6) and the female receptor having key slots (9) that receive the key portions (column 3, lines 15-25, 48-50, column 4, lines 12-20, 26-39).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the balls and sockets of Belson with the projections and slots, as taught by Wolfe, to control the amount of displacement about the axis of the male and female connectors (column 3, lines 15-25).

The Examiner notes that the device of Belson is capable of having a medical implant mounted thereon to be advanced through a catheter. Regarding the limitation, "whereby a medical implant mounted at one end of the device can be advanced through a catheter by pushing on the other end of the device, the hinged connections allowing the device to follow a curved path through the catheter, characterized in that each segment is detachable from its adjacent segment(s)", the Examiner notes that the manner or method in which an device is to be utilized is not germane to the issue of patentability of the device itself (In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967)). Furthermore, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

9. Regarding claims **17,** Belson discloses a segment having an internal passage (84) that would allow a guide wire to pass therethrough ([0072], Fig. 7A).

10. Regarding claims **19,** Belson discloses each segment having an internal passage (84) that is spaced from the segment's outer circumference and extends through the segment ([0072], Fig. 7A).

11. Regarding claim **22**, Wolfe teaches segments that snap-fit into adjacent segments (column 4, lines 1-5).

12. Regarding claim **25**, the combination of Belson discloses segments that appear to have lengths that are less than or equal to their diameters (Fig. 7A).

13. Regarding claim **27**, Wolfe teaches projections (6) that protrude from the ball (2) and slots (9) that extend along a wall of the socket (3) (column 4, lines 12-30).

14. Regarding claim **28**, Wolfe teaches slots (9) that are aligned along the same plane of the projections (6) (column 4, lines 12-30).

15. Regarding claims **29,** Belson discloses a catheter that is at least partially spaced from the outer surfaces of the segments [0093].

16. **Claims 6, 8, 18, 26 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belson (US PGPub No. 2003/0032859A1) in view of Wolfe (US Patent No. 5,486,127), as applied to claims 1, 16 and 30 above, and further in view of Danitz et al. (US PGPub No. 2004/0236316A1).**

17. Regarding claim **6**, the combination of Belson and Wolfe discloses all of the limitations previously discussed except for a device having 15 segments

Danitz et al. teaches a device having 15-80 segments (Fig. 1F) or any number of links and link pairs dependent on the body region of use and desired length of the articulating mechanism ([0048]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the combination of Belson and Wolfe with 13 to 80 segments, as taught by Danitz et al., to provide an overall length of the device

that is dependent on the intended body region of use and desired length of the articulating mechanism [0048].

18. Regarding claims **8, 18 and 31**, Danitz et al. discloses a channel defined on an outer surface of the socket wall that are aligned along a common path ([0020], Fig. 5A).

19. Regarding claim **26,** Danitz et al. teaches segments having diameters ranging from 0.5mm to 15mm which is within the claimed range of 10mm or less [0034].

20. **Claims 11, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belson (US PGPub No. 2003/0032859A1) in view of Wolfe (US Patent No. 5,486,127), as applied to claim 1 above, and further in view of Geitz (US Patent No. 6,146,389).**

21. Regarding claim **11 and 12**, the combination of Belson and Wolfe discloses all of the limitations previously discussed except for a medical implant mounted on one end of the device.

Geitz teaches a stent deployment device having a stent, a “vascular graft”, or a “medical implant" (22) circumferentially compressed over the protective cap (20) at the distal end of a flexible endoscope or “articulated device “(10) (column 3, lines 12-15, line 37 and 44-45). Please see figure 1.

Therefore, it would have been obvious to one of ordinary skill in the art to have applied the known technique of attaching an implant to the distal end of an endoscope of the combination of Belson and Wolfe, as taught by Geitz, for the predictable result of deploying a stent within a body cavity in a minimally invasive manner and having increased flexibility and maneuverability for positioning a stent within a vessel.

22. Regarding claim **15,** Belson discloses a device including a plurality of detachable, hingeably connected segments, each segment being hingeably connected to two adjacent segments or a single adjacent segment if at the end of the line, each segment connected by a ball-and-socket type joint wherein a male part engages within the socket of a female (0025, 0072, 0076], Fig. 7A). The endoscope of Belson may be inserted into a body cavity through a surgical tube such as a surgical cannula or introducer [0093]. Although Belson fails to expressly disclose the surgical tube as a catheter, it is well known in the art to introduce an endoscope into a body through a large diameter tube such as a catheter by pushing on an end of the endoscope. A medical implant is capable of being attached to an end of the device and can be advanced through the catheter by pushing the other end of the device. However, Belson fails to expressly disclose segments bearing a male part including a pair of projections and a female part including a socket with slots and an implant mounted on one end of the device.

Wolfe teaches a system having a plurality of segments connected by ball-and-socket type joints, each segment including a male connector (2) and a female receptor(3), the male connector having adjoining keys (6) and the female receptor having key slots (9) that receive the key portions (column 3, lines 15-25, 48-50, column 4, lines 12-20, 26-39).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the balls and sockets of Belson with the projections and slots, as taught by Wolfe, to control the amount of displacement about the axis of the male and female connectors (column 3, lines 15-25).

Geitz teaches a stent deployment device having a stent, a “vascular graft”, or a “medical implant" (22) circumferentially compressed over the protective cap (20) at the distal end of a flexible endoscope or “articulated device “(10) (column 3, lines 12-15, line 37 and 44-45, column 5, lines 20-34).

Therefore, it would have been obvious to one of ordinary skill in the art to have applied the known technique of attaching an implant to the distal end of an endoscope of the combination of Belson and Wolfe, as taught by Geitz, for the predictable result of deploying a stent within a body cavity in a minimally invasive manner and having increased flexibility and maneuverability for positioning a stent within a vessel.

23. Claims 16-19, 22, 25, 26, 29 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Danitz et al. (US PGPub No. 2004/0236316A1) in view of Van Hoose (US Patent No. 4,114,401).

24. Regarding claim **16**, Danitz et al. discloses a device including a plurality of detachable, hingeably connected segments attached by corresponding ends whereby a medical implant attached to an end of the device can be advanced through a catheter by pushing the other end of the device ([0030], Figs. 3a-3c, 10, 11). Danitz et al. discloses a catheter having an interior passage wherein multiple segments are arrayed within, each segment pivotally abuts adjacent segments and may adopt a curved path within the catheter, the segments are translatable within the passage, whereby the segment at one end of the line can:

(i) can have a medical implant situated thereon, and

(ii) can be advanced through at least a major portion of the length of the catheter interior passage to eject the medical implant from a passage exit [0060].

Examiner notes that the device of Danitz et al. is capable of having a medical implant mounted thereon to be advanced through a catheter. Regarding the limitation, "whereby a medical implant mounted at one end of the device can be advanced through a catheter by pushing on the other end of the device, the hinged connections allowing the device to follow a curved path through the catheter, characterized in that each segment is detachable from its adjacent segment(s)", the Examiner notes that the manner or method in which an device is to be utilized is not germane to the issue of patentability of the device itself (In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967)).

However, Danitz et al. fails to disclose each segment bearing a ball thereon, the ball having projections extending therefrom, wherein each projection is engaged to an adjacent segment.

Van Hoose teaches a universal joint including a spherical ball (114) having a bore wherein a drive pin (128) is disposed to produce two projections (132, 134) from the ball which is slidably disposed within a socket (12) and slots (118, 120) that receive the projections of the ball (column 3, lines 34-51).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the joint of Danitz et al. with the universal joint of Van Hoose, to provide multiple degrees of freedom.

25. Regarding claims **17 and 19**, Danitz et al. discloses a segment having an internal passage spaced from the segment's outer circumference (Fig. 3A).

26. Regarding claims **18 and 31,** Danitz et al. discloses a channel defined on an outer surface or outer circumference of the socket wall that are aligned along a common path ([0020], Fig. 3A, 5A).

27. Regarding claim **22**, Van Hoose teaches segments that snap-fit to an adjacent segment (column 3, lines 44-47, Figs. 5, 6).

28. Regarding claim **25**, the combination of Danitz et al. and Van Hoose discloses the claimed invention except for segments having lengths that are less than or equal to their diameters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the segments having lengths that are less than or equal to their diameters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

29. Regarding claim **26**, Danitz et al. discloses segments having diameters ranging from 0.5mm to 15mm which is within the claimed range of 10mm or less [0034].

30. Regarding claim **28**, Van Hoose teaches slots (118, 120) that are aligned along the same plane of the projections (132, 134) (column 3, lines 33-51, Figs. 5, 6).

31. Regarding claim **29**, Danitz et al. discloses a catheter that is partially spaced from the outer surfaces wherein the segments may be threaded within the passage [0060].

32. Regarding claim **30**, Van Hoose teaches projections (132, 134) that protrude from a ball (114), a socket (112) bounded by a wall having slots (118, 120) that extend along a wall of the socket (112) wherein the ball is received within the socket of an adjacent segment and the projections are received within the slots (column 3, lines 33-51, Figs. 5, 6).

Response to Arguments

33. Applicant's arguments, filed 21 September 2009, with respect to claims 1 and 15 respectively citing Greenwood, Sr. et al. and Geitz, have been fully considered and are persuasive. The rejection has been withdrawn due to the amendments that were made to claim 1.

34. Applicant's arguments filed 21 September 2009 have been fully considered but they are not persuasive. The Applicant contends that the substitution of the joint of Danitz et al. with the universal joint of Van Hoose would disadvantageously decrease the degrees of freedom of Danitz. The Applicant refers to figures 1A-1B wherein cables connect the segments to allow free rotation. However, the substitution of Van Hoose would provide a more secure engagement between the male and female parts of the segments that would reduce the wear of the cables of Danitz, thus enhance the multiple degrees of freedom and strengthen the articulating angles of the segments. The Applicant contends that an ordinary artisan would not utilize and internal passage when using a Van Hoose joint since the projections are restrained within the slots. However, the projections of the pin within the Van Hoose joints are not restrained within the slots but are free to oscillate within the slots of the ball such that a channel within the

connected segments would not disrupt the movement of the pin and would allow communication between segments. The claim fails to specify the location of the lumen, however, Danitz teaches a lateral location of the passage within the segments that would allow a guide wire to pass therethrough and would not inhibit movement therein. The Applicant contends that the ball of Van Hoose fails to snap-fit within the socket, however, when pushed into the socket of the joint, the ball fits therein, thus creating a workable joint.

Conclusion

35. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is

(571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
12/28/2009
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
1/5/10